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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/412,558	10/05/1999	JUALANG HWANG	08919/022001	9802
26161	7590	07/13/2004	EXAMINER	
<b>FISH &amp; RICHARDSON PC</b> 225 FRANKLIN ST BOSTON, MA 02110				DEVI, SARVAMANGALA J N
		ART UNIT		PAPER NUMBER
		1645		

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

*SMA*

### Office Action Summary

Application No.	Applicant(s)	
09/412,558	HWANG ET AL.	
Examiner	Art Unit	
S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 26 April 2004.  
2a) This action is FINAL.                    2b) This action is non-final.  
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 24-27 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) Claim(s) 25-27 is/are allowed.  
6) Claim(s) 24 is/are rejected.  
7) Claim(s) \_\_\_\_\_ is/are objected to.  
8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:  
    1. Certified copies of the priority documents have been received.  
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
    Paper No(s)/Mail Date \_\_\_\_\_.  
4) Interview Summary (PTO-413)  
    Paper No(s)/Mail Date \_\_\_\_\_.  
5) Notice of Informal Patent Application (PTO-152)  
6) Other: \_\_\_\_\_.

## **RESPONSE TO APPLICANTS' AMENDMENT**

### **Applicants' Amendment**

1) Acknowledgment is made of Applicants' amendment filed 04/26/04 in response to the non-final Office Action mailed 12/23/03.

### **Status of Claims**

2) Claims 14, 15, 17 and 18 have been canceled via the amendment filed 4/26/04.

Claims 24-27 have been amended via the amendment filed 4/26/04.

Claims 24-27 are pending and are under examination.

### **Prior Citation of Title 35 Sections**

3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

### **Prior Citation of References**

4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

### **Rejection(s) Moot**

5) The rejection of claims 14 and 18 made in paragraph 12 of the office Action mailed 03/10/03 (paper no. 15) and maintained in paragraph 7 of the Office Action mailed 07/08/03 (paper no. 17) and paragraph 8 of the Office Action mailed 12/23/03 under 35 U.S.C § 102(e) as being anticipated by Lorberboum-Galski *et al.* (US 6,140,066, filed 24 March 1998, already of record) as evidenced by Burnie *et al.* (EP 0 406 029), is moot in light of Applicants' cancellation of the claims.

6) The rejection of claims 14, 15, 17 and 18 made in paragraph 13 of the Office Action mailed 03/10/03 (paper no. 15) and maintained in paragraph 8 of the Office Action mailed 07/08/03 (paper no. 17) and paragraph 9 of the Office Action mailed 12/23/03 under 35 U.S.C § 102(b) as being anticipated by Hickey *et al.* (WO 97/15325 - already of record), is moot in light of Applicants' cancellation of the claims.

7) The rejection of claims 14, 15, 17 and 18 made in paragraph 11 of the Office Action mailed 12/23/03 under 35 U.S.C. § 101 as being directed to non-statutory subject matter, is moot in light of Applicants' cancellation of the claims.

8) The rejection of claim 14 made in paragraph 13 of the Office Action mailed 12/23/03 under

35 U.S.C. § 102(b) as being anticipated by Gray *et al.* (*PNAS* 81: 2645-2649, 1984) as evidenced by Covacci *et al.* (WO 93/18150), is moot in light of Applicants' cancellation of the claim.

9) The rejection of claims 14, 15, 17 and 18 made in paragraph 14 of the Office Action mailed 12/23/03 under 35 U.S.C. § 103(a) as being unpatentable over Hickey *et al.* (WO 97/15325 - already of record) in view of Russell-Jones *et al.* (WO 91/02799 - already of record), is moot in light of Applicants' cancellation of the claims.

#### **Rejection(s) Withdrawn**

10) The rejection of claims 24-27 made in paragraph 11 of the Office Action mailed 12/23/03 under 35 U.S.C. § 101 as being directed to non-statutory subject matter, is withdrawn in light of Applicants' amendment to the claims.

11) The rejection of claims 24-27 made in paragraph 15 of the Office Action mailed 12/23/03 under 35 U.S.C. § 103(a) as being unpatentable over Hickey *et al.* (WO 97/15325 - already of record) in view of Hwang *et al.* (*J. Biol. Chem.* 264: 2379-2384, 1989 - Applicants' IDS) (Hwang *et al.*, 1989) or Hwang *et al.* (US 6,387,684) ('684) and Pastan *et al.* (US 4,892,827 - already of record), is withdrawn. A modified rejection is made herebelow to reject the claims, as amended.

12) The rejection of claim 24 made in paragraph 12 of the Office Action mailed 12/23/03 under 35 U.S.C. § 102(b) as being anticipated by Gray *et al.* (*PNAS* 81: 2645-2649, 1984) as evidenced by Covacci *et al.* (WO 93/18150), is withdrawn in light of Applicants' amendment to the claim.

#### **New Rejection(s)**

Applicants are asked to note the following new rejection(s) made in this Office. The new rejections are necessitated by Applicants' amendments to the claim(s).

#### **Rejection(s) under 35 U.S.C § 102**

13) Claim 24 is rejected under 35 U.S.C. § 102(b) as being anticipated by Lukac *et al.* (*Infect. Immun.* 56: 3095-3098, 1988) as evidenced by Gray *et al.* (*PNAS* 81: 2645-2649, 1984, already of record) and Covacci *et al.* (WO 93/18150 - already of record).

The transitional limitation "comprises" similar to the limitations such as, "has", "includes," "contains," or "characterized by," represents open-ended claim language and therefore does not exclude additional, unrecited elements. See M.P.E.P 2111.03 [R-1]. See *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising"

leaves “the claim open for the inclusion of unspecified ingredients even in major amounts”). On the other hand, the limitation “consisting of” represents closed claim language and excludes any element, step, or ingredient not specified in the claim. *In re Gray*, 53 F.2d 520, 11 USPQ 255 (CCPA 1931); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948).

Lukac *et al.* taught an isolated *Pseudomonas* DNA which encodes an exotoxin A polypeptide wherein the polypeptide has a deletion of an amino acid at position 553 and is devoid of toxicity (see Results section). That this DNA encodes a polypeptide that comprises: (a) a *Pseudomonas* exotoxin A fragment consisting of the receptor binding domain; and (b) at least two copies an antigenic peptide sequence, ala ala gly glu, one at positions 375-378 and another at positions 523-526 of the polypeptide, is inherent from the teachings of Lukac *et al.* in light of what is known in the art. For instance, Gray *et al.* taught that an isolated *Pseudomonas* DNA which encodes an exotoxin A polypeptide wherein the polypeptide comprises: (a) a *Pseudomonas* exotoxin A fragment consisting of the receptor binding domain, i.e., 1-252 amino acid residues of *Pseudomonas* exotoxin A; and (b) at least two copies an antigenic peptide sequence, ala ala gly glu, one at positions 375-378 and another at positions 523-526 of the polypeptide. See Figure 1; Materials and Methods; and Results of Gray *et al.* That the prior art *Pseudomonas* exotoxin A represents a polypeptide that ‘comprises’ a *Pseudomonas* exotoxin A fragment consisting of the receptor binding domain of *Pseudomonas* exotoxin A is inherent from the teachings of Gray *et al.* That the 4 amino acid-long peptide sequences, ala-al-a-gly-glu, in the prior art exotoxin A serve as antigenic peptides is inherent from the teachings of Lukac *et al.* in light of what is well known in the art. For instance, Covacci *et al.* disclosed that a peptide comprising three amino acids will have the spatial conformation unique to an epitope or antigenic determinant (see paragraph bridging pages 14 and 15 of Covacci *et al.*).

Claim 24 is anticipated by Lukac *et al.* Gray *et al.* or Covacci *et al.* is **not** used as a secondary reference in combination with Lukac *et al.*, but rather is used to show that every element of the claimed subject matter is disclosed by Lukac *et al.* See *In re Samour* 197 USPQ 1 (CCPA 1978).

#### Remarks

- 14) Claim 24 stands rejected. Claims 25-27 are allowable.
- 15) Applicants’ amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

**16)** Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

**17)** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**18)** Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system. A message may be left on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*S. Devi, Ph.D.*  
**PRIMARY EXAMINER**